

REMARKS

The following remarks are submitted to be fully responsive to the final Official Action dated February 5, 2008. This response is thus timely submitted within the three-month shortened statutory period for response. Should any fees be required, the Commissioner is authorized to charge Kagan Binder Deposit Account No. 50-1775 and thereafter notify us of the same. Reconsideration of all outstanding grounds of the rejection and allowance of the subject application are believed in order and respectfully requested.

In the Official Action dated February 5, 2008, the Examiner acknowledged that Applicant's arguments filed January 14, 2008, with respect to rejection of claims 1 and 32 under 35 U.S.C. 102, were persuasive, and the rejection was withdrawn. However, new grounds of rejection were set forth based on Duhaylongsod et al.

In the Official Action, claims 1-3, 5-7, 9-13, 32-34, 36-38, 40 and 41 (including independent claims 1 and 32) are rejected under 35 U.S.C. 103(a) as being unpatentable over Duhaylongsod et al. Also, claims 4 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Duhaylongsod et al. in view of Stanish, and claims 8, 14, 16-20, 39 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Duhaylongsod et al. in view of Amor et al.

In rejecting claims 1-3, 5-7, 9-13, 32-34, 36-38, 40 and 41 under 35 U.S.C. 103(a) as being unpatentable over Duhaylongsod et al., the Examiner combined two separate embodiments from the reference. The embodiment shown in Figures 5-8 was provided as disclosing the steps of: making an incision (18) in the blood vessel wall (14), inserting a tubular member (80) into a conduit (26, 12), advancing the tubular member through the incision located on a proximal end thereof, fixedly joining the conduit to the vessel wall, and after fixedly joining the conduit to the vessel, withdrawing the tubular member through the conduit. The embodiment shown in Figures 18-20 was provided as disclosing the step of providing oxygenated liquid flow through a tubular member and into the blood vessel while fixedly joining the conduit. The Examiner asserted that it would have been obvious to utilize the tubular member and conduit from the embodiment of Figures 18-20 in the embodiment of Figures 5-8 in order to provide blood through the tubular member and into the vessel during an anastomosis procedure.

Applicants assert, however, that it does not make sense to combine the two separate embodiments of Duhaylongsod et al. in such a way as presented by the Examiner. In the embodiment in Figures 18-20, first, the catheter 90 is not inserted into the conduit 12 itself, but instead into an elongated member 60 of a fastener 50 to which the conduit 12 is attached. The

catheter 90 is also provided within a blood vessel (such as in a well known approach), and is not advanced into the blood vessel through an incision (at anastomosis site) at any time during the disclosed process. Further, the distal end of the conduit 12 is not fixedly joined to the blood vessel. The proximal end of the conduit 12 is joined to the elongated member 60 of the fastener 50, and the fastener 50 is positioned such that the conduit 12 extends through the center of the incision in the blood vessel wall. The conduit 12 then is not itself fixedly joined to the blood vessel. Additionally, the catheter 90 is not withdrawn through the conduit 12, but is withdrawn through the elongated member 60 of the fastener 50.

The catheter 90, in the embodiment of Figures 18-20, preferably has three balloons (92, 94, 96) with the farthest upstream balloon (92) inflated to function to occlude or block the flow of blood at the anastomosis site. Balloons 94, 96 function to expand end portion 56 of the fastener 50 to opposite sides of an incision in a blood vessel. There are openings 98 located on catheter 90 through which blood flow is supplied downstream. If the catheter 90 of the embodiment of Figures 18-20 were used in the embodiment in Figures 5-8, in place of catheter 80, the catheter would be inserted at the anastomosis site itself. Thus, it would not be possible for balloons on the catheter to be located upstream from the anastomosis site for the purpose of occlusion of the vessel at the anastomosis site, while the openings would be downstream to supply blood downstream from the occlusion. Thus, the two separate embodiments, as described by the Examiner, of Duhaylongsod et al. are not properly combinable to result in all elements of claim 1 being disclosed, taught or suggested in the reference in order to render claim 1 unpatentable under 35 U.S.C. 103.

Accordingly, it is submitted that the Duhaylongsod et al. reference does not render claim 1 obvious. Allowance of independent claim 1 and dependent claims 2-3, 5-7, 9-13 (including withdrawn claim 15) is therefore respectfully requested.

Regarding independent claim 32, it is submitted that similar distinguishing aspects are claimed over the Duhaylongsod et al. reference. Also, claim 32 recites a method of joining a blood conduit and a blood vessel, where a distal region of the conduit is fixedly joined to the blood vessel proximal end. This procedure is further distinct from the technique of the Duhaylongsod et al. reference, which does not disclose a graft connection to or near an end of any blood vessel. So, in addition to distinguishing on a similar basis as claim 1, claim 32 is further patentably distinct on the type of joining that is created according to the claim steps. Allowance of independent claim 32 and dependent claims 33-34, 36-38, 40 and 41 is also believed proper and respectfully requested.

Claims 4 and 35 are dependent upon claims 1 and 32, respectively. Therefore, based upon the discussion above, claims 4 and 35 are similarly not rendered obvious by Duhaylongsod et al. Claims 4 and 35 are rejected as being unpatentable over Duhaylongsod et al. in view of Stanish. Stanish does not remedy any deficiencies of Duhaylongsod et al. in order to render claim 4 and 35 unpatentable.

In the Official Action, with regard to claim 4 and 35, the Examiner provided that Duhaylongsod et al. failed to disclose fixedly joining, including suturing, the conduit to the blood vessel, and further provided that such suturing was disclosed by Stanish. Stanish discloses suturing of a graft to a vein, but the reference is not properly combinable with Duhaylongsod et al.

In Duhaylongsod et al., suturing of the conduit 26, 12 is not necessary or desired. For example, in the embodiment of Figures 5-8, the graft vessel 12 or conduit is attached to a fastener 10 that is expanded using a balloon catheter 80 in order to seal the graft vessel 12 to the artery. There is no need for sutures in that embodiment. In the embodiment of Figures 18-20, for another example, the conduit is attached or sutured to a fastener 50 that is joined to the blood vessel when balloons on catheter 90 are inflated and expand the ends of the fastener 50 to press against the inside of the blood vessel wall. There is also no need for sutures in that embodiment. Duhaylongsod et al. actually teaches away from using sutures to join a conduit to a blood vessel, and teaches the use of expandable fasteners instead. The specification of Duhaylongsod et al. even provides that an aspect of the invention is to allow two vessels to be “sealingly secured to one another without the need for sutures” (col. 1, lines 52-54).

Accordingly, it is submitted that the Duhaylongsod et al. in view of Stanish do not render claims 4 and 35 obvious. Allowance of claims 4 and 35 is therefore respectfully requested.

Claims 8, 14, 16-20, 39 and 42 are dependent upon independent claims 1 and 32. Therefore, based upon the discussion above, these claims are similarly not rendered obvious by Duhaylongsod et al. Claims 8, 14, 16-20, 39 and 42 are rejected as being unpatentable over Duhaylongsod et al. in view of Amor et al. Amor et al., however, does not remedy any deficiencies of Duhaylongsod et al. in order to render claim 8, 14, 16-20, 39 and 42 unpatentable.

In rejecting claims 8, 14, 16-20, 39 and 42 as being unpatentable over Duhaylongsod et al. in view of Amor et al., the Examiner provided that Duhaylongsod et al. failed to disclose “inserting a stiffening member within the tubular member and wherein the expanding includes forcing the oxygenated fluid under pressure through the tubular member to expand the weakened distal region and into the blood vessel.”

Amor et al. discloses a device used to implant or deliver stents to arteries. The device includes a stent pusher portion 2 comprising a microcatheter 4 with a guidewire 6 extending through a lumen 5 in the microcatheter 4. The device also includes a stent loading cavity 7 able to retain a stent 7, which is self-expanding. The distal end 9 of the device includes an atraumatic tip 10 which is prolonged by a tip balloon part 11 comprising an inflatable occlusive balloon 12 and a fluid releasing section 13. When the device is inserted into a body, the tip balloon part 11 leads the device. The shape of the tip balloon part 11, when the balloon 12 is deflated, is able to be changed to fit through the vascular system by advancement of the guidewire 6 more or less into the tip balloon part 11. The balloon 12 can be inflated to hermetically close the vessel upstream with respect to the stenosis to be cured. The fluid-releasing section 13 on the proximal face of the balloon 12, or just there behind, provides a flushing action upstream from the stent 7 placement in order to clean the vasculature. The fluid used for flushing is described as a physically acceptable fluid. The flushing action begins when the balloon 12 pressure reaches a given value, thus activating a controlled leak via the fluid-releasing section 13.

Amor et al. is not properly combinable with Duhaylongsod et al. For example, in Duhaylongsod et al., an anastomosis procedure is described, not an angioplasty procedure, as in Amor et al. In the anastomosis procedure of Duhaylongsod et al., for the embodiment shown in Figures 5-8, a blood conduit 12 is fastened into the blood vessel 14 using a fastener in order to bypass the stenosis 74 or blockage. Therefore, if a fluid was provided through the conduit 12 it would not be able to flush the blockage area because that area is bypassed. Regarding the embodiment in Figures 18-20 of Duhaylongsod et al., the conduit 12 is attached to the fastener 50 that is placed in a blood vessel 14, which does not even contain a blockage. Thus, there is no need to flush with a fluid in the embodiments shown in Duhaylongsod et al. Therefore, the Amor et al. and Duhaylongsod et al. references are not properly combinable.

Even if the two references were properly combinable, Amor et al. does not remedy the deficiencies of Duhaylongsod et al. For example, Amor et al. does not even disclose using an oxygenated fluid. In addition, there is no flow restrictor or bulb addressed by the two references, as in claims 8, 16 and 39 of the present invention. Therefore, claims 8, 14, 16-20, 39 and 42 are not unpatentable.

It is submitted that claims 1-20 and 32-42 are currently in condition for allowance, a notice of which is earnestly solicited. If the Examiner finds any issue remaining after consideration of this response, the Examiner is invited to contact the undersigned, at the Examiner's convenience, in order to expedite any remaining prosecution.

Respectfully Submitted,

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